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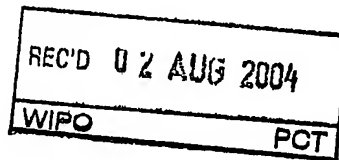
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FEE RECORD SHEET

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)					
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<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max) NEEDLELESS PUSH-RELEASE INJECTOR					
Direct all correspondence to:			CORRESPONDENCE ADDRESS		
<input checked="" type="checkbox"/> Customer Number 26822			 Place Customer Number Bar Code here PATENT TRADEMARK OFFICE		
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages	9	<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s)		Number of Sheets	2	<input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:				08-0114	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.				\$160.00	
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE



Date 08/26/2003

TYPED or PRINTED NAME WALTER A. HACKLER, Ph.D.

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(if appropriate)
Docket Number: 3032P

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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P19LARGE/REV05

NEEDLELESS PUSH-RELEASE INJECTOR

A needleless push-release injector in accordance with the present invention generally includes a housing having a distal end, a proximal end, and a central bore. A cocking ring is provided and extends from the housing distal end and includes a rear portion slidably disposed within the housing bore.

A cylinder is slidably disposed within the cocking ring and includes a front end and a rear end with a chamber disposed proximate the front end.

A vial for containing a medicament, such as, for example, BOTOX®, is provided and is disposed in the housing proximal end with the vial being in fluid communication with the chamber. In addition, an injection head is disposed at the cylinder front end and is in fluid communication with the chamber.

A piston slidably disposed within the cocking ring and includes a front head slidably disposed within the cylinder and a rear head slidably disposed within the housing bore. The front head is fitted within the cylinder in order to draw medicament from the chamber through a one-way valve upon movement of the piston from a first position to a second position and to force medicament through the injection head from the chamber upon movement of the piston from the second position to the first position. A spring is disposed between

the housing proximal end and a piston causing biasing of the piston.

5 A sear is provided for releasably holding the spring compressed. The sear includes a sear spring and a tapered end with the sear spring causing releasable engagement of the tapered end with the piston rear head.

10 The cylinder rear end is disposed in an operational relationship with the sear tapered end for releasing a sear from the piston rear head enabling the spring to drive the piston to the first position. This release and movement is caused by force against the injection head and cylinder due to contact with skin of a patient.

15

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may be more clearly understood with reference to the appended drawings of which:

20

Figure 1a is a perspective view of a needleless push-release injector in accordance with the present invention generally showing a housing, cocking ring, Figure 1b is a perspective view of the present invention illustrating
25 internal components including a vial, check valve, piston, spring, along with the cocking ring and injection head as shown in Figure 1a;

Figure 2 is a cross-sectional view of the injector shown in Figures 1a, 1b, more particularly illustrating components of the present invention in which the spring is held in the compressed state by a sear prior to release for injection of medicament through an injection head into the patients skin, not shown in Figure 2;

Figure 3 is a cross-sectional view similar to that shown in Figure 1 illustrating release of the piston upon pressure being applied to the injection head by the skin of a user; and

Figure 4 is a perspective view of the injection head cylinder piston and cocking ring illustrated.

15 DETAILED DESCRIPTION

With reference to Figures 1a and 1b there is shown a needleless push-release injector 10 in accordance with the present invention generally showing a housing 12 along with a cocking ring 14, a cylinder 16, injection head 18, a vial 20, piston 22, valve 24, and a spring 26. With reference to Figures 2 and 3, a housing 12 includes a distal end 30 and a proximal end 32 with a bore 34 therein. The cocking ring 14 extends from the housing distal end 30 and includes a rear portion 38 disposed within the housing bore 34.

The cylinder 16 is slidably disposed within the cocking ring 14 and includes a front end 42 and a rear end 44 with a chamber 46 disposed proximate the front end 42. A vial 50 for

containing a medicament is replaceably disposed proximal end 32 and is in fluid communication with the chamber 46 through a dip tube 24 and check valve 24.

5 The injection head 18 is disposed at the cylinder front end 42 and in fluid communication with the chamber 46. The injection head may be of any suitable design.

10 A piston 64 is slidably disposed within the cocking ring 14 and includes a front head 66 slidably disposed within the cylinder 16 and a rear head 68 slidably disposed within the housing bore 34.

15 The front head 66 is fitted to the cylinder 16 in order to draw medicament from the vial 50 into the chamber through the one-way valve 24 upon movement of the piston 64 from a first position shown in Figure 3 to a second position shown in Figure 2. Movement of the piston from the first position to the second position forces medicament from the chamber 46
20 through the injection head 18.

25 A main spring 72 is disposed between the housing proximal end 32 and the piston rear head 68 and a sear 80 is provided for releasably holding of the piston 64 in the second position with the main spring 72 compressed. The sear 80 includes a sear spring 82 and a tapered end 84 which provides releasable engagement with the piston rear head 68.

In use, the injector head 18 is pressed against the skin 60 which causes rearward motion of the cylinder 16 and the cylinder rear end 44 is urged against the tapered end 84 causing movement of the sear in the direction of the arrow 90 and compression of the sear spring 82 which releases the piston rear head 68 and piston 64, thus causing the spring 72 to force the piston front head 66 into the chamber 46 forcing medicament through the injection head 18, as indicated by the arrow 70.

10

To re-cock the device the cocking ring 14 is moved in the direction of the arrow 94, thus moving the piston end 84 and re-engagement of the sear 80 with the piston rear head 68.

15

As illustrated in Figure 4, the cocking ring may include guides 96 for preventing rotation thereof.

Although there has been hereinabove described a specific needleless push-release injector in accordance with the present invention for the purpose of illustrating the manner in which the invention may be used to advantage, it should be appreciated that the invention is not limited thereto. That is, the present invention may suitably comprise, consist of, or consist essentially of the recited elements. Further, the invention illustratively disclosed herein suitably may be practiced in the absence of any element which is not specifically disclosed herein. Accordingly, any and all modifications, variations or equivalent arrangements which may occur to those skilled in the art, should be considered to be

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within the scope of the present invention as defined in the appended claims.

WHAT IS CLAIMED IS:

1. A needleless push release injector comprising:
 - a housing having a distal end, a proximal end and a
5 central bore;
 - a cocking ring extending from the housing distal end
and having a rear portion slidably disposed in the housing
bore;
 - a cylinder slidably disposed within said cocking
10 ring and having a front end and a rear end with a chamber
disposed proximate the front end;
 - a vial for containing a medicament is disposed in
the housing proximal end and in fluid communication with said
chamber;
 - 15 an injection head disposed at the cylinder first end
and in fluid communication with the chamber;
 - a piston slidably disposed within said cocking ring
and having a front head slidably disposed within said cylinder
and a rear head slidably disposed within the housing bore, the
20 front head being fitted to said cylinder in order to draw
medicament from said vial into said chamber through a one-way
valve upon movement of said piston from a first position to a
second position and to force medicament through the injection
head upon movement of the piston from the second position to
25 the first position;
 - a spring disposed between the housing proximal end
and a rear head of said piston; and
 - a sear for releasably holding said piston in the
second position with the spring compressed, said sear

3032

including a sear spring and a tapered end, the sear spring causing releasable engagement of said tapered end with the piston rear head; and

5 said cylinder rear end disposed in an operational relationship with the sear tapered end for releasing said sear from the piston rear head enabling said spring to drive said piston to said first position.

ABSTRACT

5 A needleless push-release injector includes a housing, a
cocking ring extending from the housing and a cylinder
disposed within the cocking ring and housing bore. A vial is
provided for containing a medicament and an injection head is
disposed at a cylinder front end and in fluid communication
with the chamber. A piston is slidably disposed within the
cocking ring and includes a front head slidably disposed
10 within the cylinder and a rear head slidably disposed within
the housing bore. A spring disposed within the housing
proximal end and a rear head is provided along with a sear for
releasably holding the piston in the second position with the
spring compressed. Pressure against the injection head causes
15 release of the piston and injection of medicament through the
injector head and patients skin. The cocking ring enables
resetting of the spring and withdrawal of medicament from the
vial into the injection chamber.



ALLERGAN

Needleless Push-Release Injector

SPIKE/DIPTUBE VALVE

D

CHECK VALVE

PISTON

COCKING RING

10

14

16

18

PRESSURE
FIRES INJECTION

MAINSRING

HATCH

FIG 1b

INJECTION HEAD 18

MANIFOLD

FIG 1a

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FIG 2

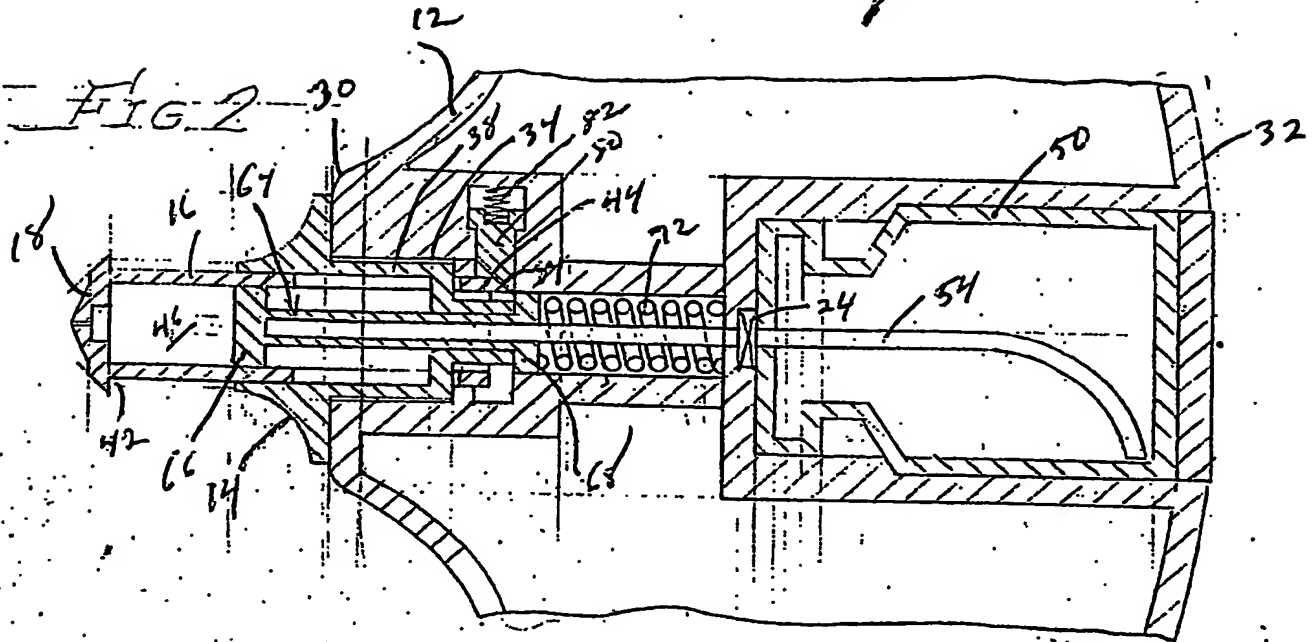


FIG 3

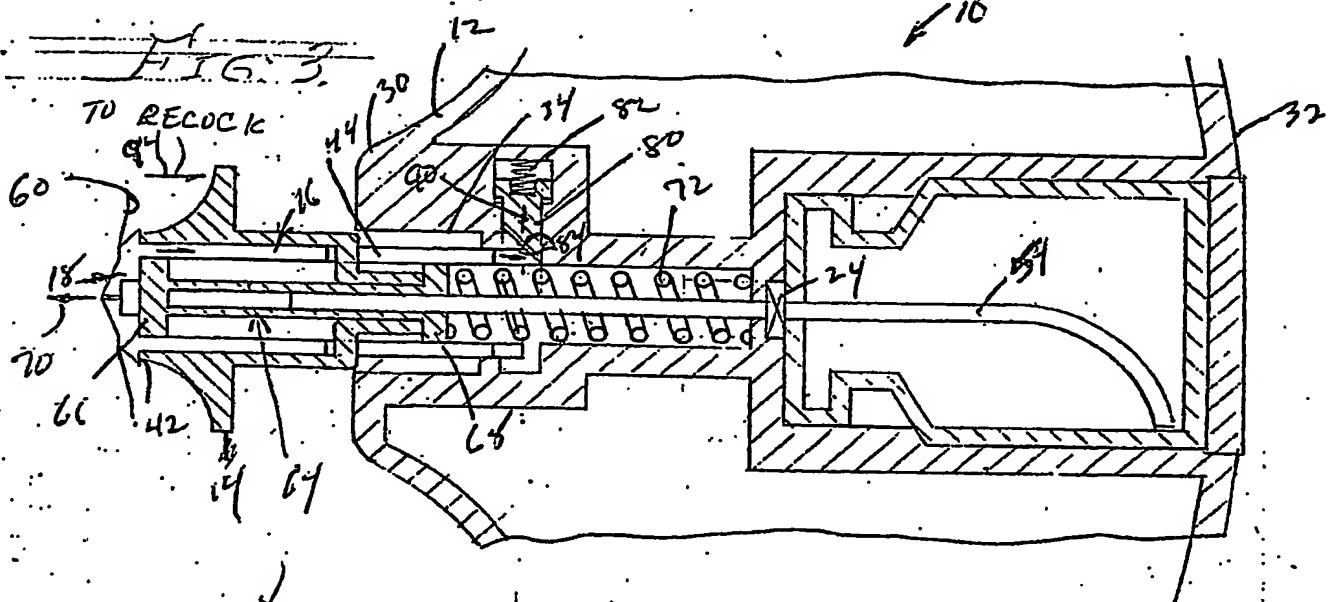
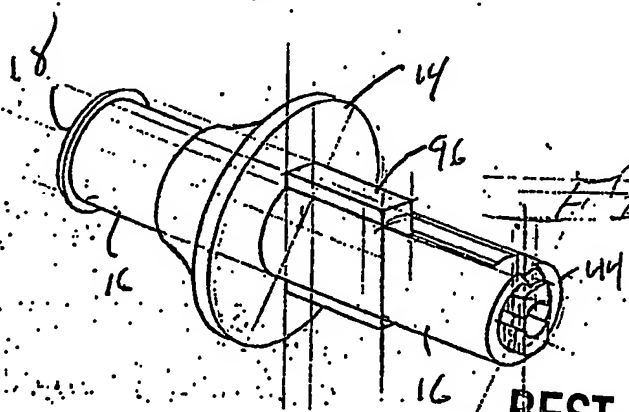


FIG 4



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